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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,327	10/04/2001	Yong Ho Kang	60034-301801	2655

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EXAMINER

PAK, YONG D

ART UNIT PAPER NUMBER

1652

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,327

Applicant(s)

KANG, YONG HO

Examiner

Yong D Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/KR00/00026. The amendment filed on October 27, 2003, amending claim 1 and adding claims 6-9, has been entered.

Claims 1-2 and 6-9 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is drawn to a fusion enzyme wherein an oligonucleotide is not used as the linker between the two fused enzymes and claim 8 is drawn to a fusion enzyme wherein a peptide is not used as the linker between the two fused enzymes. The specification is silent on types of linkers used between the oxidase and hemoglobin. The specification does describe a fusion protein gene wherein the oxidase and

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hemoglobin in fused through overlapping primers. However, the specification lacks any description on non-oligonucleotide linkers, peptide linkers or other types of linkers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 6 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khang et al. in view of Dalboge et al.

Khang et al. (cited on previous PTO-892) teach co-expression of a D-amino acid oxidase (DAO) and *Vitreoscilla* hemoglobin (VHb) in *Escherichia coli* (page 43). A vector comprising both genes was constructed so that VHb may aid in dissolving the oxygen-limitation problem in immobilizing the DAO enzyme (page 43). It is well known in the art that VHb can be applied to enhance protein production levels (Frey et al., form PTO-892) and that VHb in *E. coli* is introduced to *E. coli* to improve oxygen utilization by the cells, to obviate the problem of oxygen limitation in large-scale bioreactor cultivations in recombinant protein productions.

The difference between the reference of Khang et al. and the instant invention is that the reference of Khang et al. does not teach a fusion protein comprising the DAO and VHb proteins.

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Dalboge et al. (form PTO-892) teach a method of producing fusion proteins using PCR to link two genes (see abstract, , pages 2-8, 9-12 and claims 1 and 9). This method of Dalboge et al. does not use peptide or oligonucleotide linkers to fuse the two proteins and functions of both proteins are maintained.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a fusion protein comprising a DAAO and VHb proteins. The motivation of making a fusion protein is to facilitate co-expression of the two proteins so that VHb may aid in solving the oxygen-limitation problem in the immobilized DAAO enzyme. One of ordinary skill in the art would have had a reasonable expectation of success since making fusion proteins are well known and established in the art.

Response to Arguments

Applicant's arguments filed on October 27, 2003, with respect to claims 1-2 have been fully considered and are persuasive. The rejection of claims 1-2 under 112, 2nd paragraph, has been withdrawn due to amendment of claim 1.

Applicant's arguments filed on October 27, 2003, with respect to the rejection of claims 1-2 under 103(a), have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khang et al. in view of Huston et al.

Applicants argue that the present invention is drawn to a VHb fused with a DAO by PCR not using peptide or oligonucleotide linkers. Claims 1-2 are drawn to a fusion protein comprising a VHb and a DAO without any limitations to the linker used. The process of making fusion proteins are very well known in the art, as shown in Huston et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to fuse the two proteins together as one sequence rather than co-expressing the proteins separately.

Applicants also argue that VHb is used indirectly and neither VHb nor DAO is separately used for co-immobilization on a matrix, but a single polypeptide of VHb-DAO is used for immobilization on a matrix. However, "It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant... it is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention." (see MPEP 2144). The claims as stated above, are simply drawn to a generic fusion protein comprising a VHb and a DAO. There is

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sufficient motivation to make such fusion product as provided by Khang et al. and methods of making fusion proteins are well known and practiced in the art.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

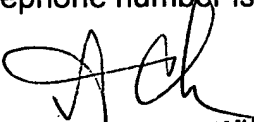
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner



PONNATHAPU ACHUTAMURTHY
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